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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/974,719	10/09/2001	Dusan Ninkov	12996.5USU1	7844

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MERCHANT & GOULD PC
P.O. BOX 2903
MINNEAPOLIS, MN 55402-0903

EXAMINER
OSTRUP, CLINTON T

ART UNIT	PAPER NUMBER
1614	11

DATE MAILED: 07/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/974,719	NINKOV, DUSAN	
	Examiner	Art Unit	
	Clinton Ostrup	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 January 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5,6,7,9* .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other:

DETAILED ACTION

Claims 1-36 are pending in this application.

Priority

Priority to Provisional US Application Numbers 60/238,501, filed October 6, 2000, 60/247,157, filed November 10, 2000, 60/277,121, filed March 19, 2001, and 60/288,531 filed May 3, 2001, has been acknowledged.

Election/Restrictions

Applicant's election of Group I, claims 1-20 in Paper No. 10 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Objections

Claim 8 is objected to because of the following informalities: It does not end with a period. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 recites the limitation "the Group I base"; however, there is insufficient antecedent basis for this limitation in the claim. There is antecedent basis for "the Group I salt" and applicant is encouraged to be consistent in their terminology.

Claims 8-10,12-13, and 15-18 are vague and indefinite because it is unclear what the percentages are based upon. It is unclear if said weight percentages are based on the total weight of the composition or if the claimed weight percentages are based on some other relative measure.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 3 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 1 of prior U.S. Patent No. 6,414,036. This is a double patenting rejection because both claims are of the same scope, that is, they are both drawn to a pharmaceutical composition comprising an antimicrobial compound and a pharmaceutically acceptable carrier, wherein the antimicrobial compound is an organic phenolic compound reacted with a Group I salt.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent

and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-2 and 4-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 and 20-23 of U.S. Patent No. 6,414,036. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both drawn to pharmaceutical compositions, comprising the same ingredients, in the same amounts and for the same purpose. Instant claim 1 requires a pharmaceutical composition for treating an infection with an antimicrobial compound and a pharmaceutically acceptable carrier, and claim 1 of U.S. Patent No. 6,414,036 requires a pharmaceutical composition comprising an antimicrobial compound, wherein said antimicrobial compound comprises an organic phenolic compound chemically reacted with a Group I salt, and a pharmaceutically acceptable carrier for treating a microbial infection. Instant claim 2 teaches the antimicrobial as an organic phenolic compound and claims 4-7, and 15-18 teach reacting the antimicrobial as being base reacted.

Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the composition of claims 1-10 and 20-23 of 6,414,036 to form the instantly claimed pharmaceutical composition of claims 1-2 and

4-20, because of the reasonable expectation that such modifications would produce a pharmaceutical composition with desired antimicrobial activities.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by The Merck Index, An Encyclopedia of Chemicals, Drugs, and Biologicals, 12th Edition, 1996, page 9539 (Merck). Merck teaches 1 gram of Thymol dissolves in 1.7 ml olive oil at 25 degrees. Since this is a claim to a composition, and the intended use of said composition is not given patentable weight unless it results in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. Since Merck teaches the specifically claimed antimicrobial compound in the specifically claimed pharmaceutically acceptable carrier, it meets the limitations of instant claims 1, 2, 4, 11.

Claim 1, 2, 19, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Avery's Drug Treatment, 4th Edition, Chapter 31, pp. 1455-1509 (Avery).

Avery teaches routes of administration of antimicrobial agents, to humans, comprising intravenous and intramuscular administration of said antimicrobial agents to treat infectious diseases caused by bacteria, which overlap those of instant claim 20. The reference teaches that intravenous administration permits administration of relatively large volumes of fluid to be used to administer the drugs. Thus, the reference clearly teaches a pharmaceutical composition for treating an infection in an animal

wherein said composition comprises an antimicrobial compound and a pharmaceutically acceptable carrier for parenteral administration, as instantly claimed in claim 1. See: page 1471, col. 2, 1.2 Routes of Administration – page 1473, col. 2, 1.2.3 Oral and Rectal Administration.

Claims 1-2, 4, 8-9, 12, and 19-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Ropapharm B.V., EP 0904780A1 (Ropapharm).

Ropapharm teaches a pharmaceutical composition in the form of a solution comprising Carvacrol (isopropyl o-cresol) and/or Thymol (applicants refer to Thymol as isopropyl-cresol), water, Emulgator 686 and polysorbate. See: page 3, col. 1, line 50 – col. 2, line 17. The reference teaches the pharmaceutical compositions as being suitable for the treatment of diseases caused by *Salamona* spp., *Pasteurella* spp., *E. coli*, *Vibrio coli*, etc. See: page 2, col. 1, line 55 – col. 2, line 5. The reference teaches the active ingredient in the form of thymol and/or carvacrol is present in an amount of 1-10% by weight, based on the total weight of the formulation. See: page 2, col. 2, lines 49-56.

Therefore, the reference teaches the specific antimicrobial compounds of instant claims 1-2, and 4 for the treatment of poultry, including turkeys as claimed in claim 19, and the use of said composition in as injectible solution comprising both thymol and carvacrol in amounts which overlap those claimed in instant claims 8-9 and 12, for the treatment of diseases caused by infections of the bacterial of claim 20.

Thus, the reference clearly anticipates instant claims 1-2, 4, 8-9, 12, and 19-20.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-2, 4, 8-9, 12, and 14-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ropapharm B.V., EP 0904780A1 (Ropapharm) as applied to claims 1-2, 4, 8-9, 12, and 19-20 above, and further in view of Avery's Drug Treatment, 4th Edition, Chapter 31, pp. 1455-1509 (Avery).

Ropapharm teaches a pharmaceutical composition in the form of a solution comprising Carvacrol and/or Thymol, water, Emulgator 686 and polysorbate as being suitable for the treatment of diseases caused by *Salamona* spp., *Pasteurella* spp., *E. coli*, *Vibrio coli*, etc. See: page 2, col. 1, line 55 – col. 2, line 5. Furthermore, the primary reference teaches the active ingredient in the form of thymol and/or carvacrol is present in an amount of 1-10% by weight, based on the total weight of the formulation.

However, the reference lacks the specific concentrations as claimed instantly in claims 14-18.

Avery teaches that the dosage regimens recommended by the manufacturers of antimicrobial drugs are purely arbitrary. The secondary reference gives guides for determining dosage amounts, but says that values will depend on the health, age, and pharmacokinetic characteristics of the patient. See: page 1489, col. 1, 4. Dosages of Antimicrobial Drugs – col. 2, 4.1 Dosages at Extremes of Age.

Moreover, while the references are silent regarding the specific percentages by weight of thymol and carvacrol as claimed instantly, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claims are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller,* 220F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

Thus, it would have been obvious to one having ordinary skill in the art at the time the inventions was made to have modified the composition of Ropapharm comprising thymol and carvacrol by adjusting the concentrations of the antimicrobial drugs as suggested by Avery because of the reasonable expectation of obtaining a composition comprising a mixture of thymol and carvacrol which would be capable of treating diseases caused by bacterial infections.

Claims 1, 2, 4, and 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over The Merck Index, An Encyclopedia of Chemicals, Drugs, and Biologicals, 12th Edition, 1996, page 9539 (Merck) and common knowledge in the art.

Merck teaches 1 gram of Thymol dissolves in 1.7 ml olive oil at 25 degrees. The Merck reference teaches a composition comprising thymol and olive oil; however, the reference lack the specific teaching of vegetable oil as a pharmaceutically acceptable carrier as claimed in claim 10.

It is common knowledge that vegetable oil is a cheap, easily obtained alternative to olive oil.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have substituted the olive oil in the composition of Merck by using a cheaper, easily obtained vegetable oil and dissolving thymol because of the reasonable expectation that thymol would have similar solubility parameters in vegetable oil.

Claims under 35 U.S.C. 103(a) as being unpatentable over Ropapharm B.V., EP 0904780A1 (Ropapharm) as applied to claims 1-2, 4, 8-9, 12, and 19-20 above and further in view of Remington's Pharmaceutical Sciences, Fifteenth Edition, 1975, pp.1405-1412.

Ropapharm teaches a pharmaceutical composition in the form of a solution comprising Carvacrol (isopropyl o-cresol) and/or Thymol (applicants refer to Thymol as isopropyl-cresol), water, Emulgator 686 and polysorbate. See: page 3, col. 1, line 50 – col. 2, line 17. The reference teaches the pharmaceutical compositions as being

suitable for the treatment of diseases caused by *Salamona* spp., *Pasteurella* spp., *E. coli*, *Vibrio coli*, etc. See: page 2, col. 1, line 55 – col. 2, line 5. The reference teaches the active ingredient in the form of thymol and/or carvacrol is present in an amount of 1-10% by weight, based on the total weight of the formulation. See: page 2, col. 2, lines 49-56.

Therefore, the reference teaches the specific antimicrobial compounds of instant claims 1-2, and 4 for the treatment of poultry, including turkeys as claimed in claim 19, and the use of said composition in as injectible solution comprising both thymol and carvacrol in amounts which overlap those claimed in instant claims 8-9 and 12, for the treatment of diseases caused by infections of the bacterial of claim 20. However, the primary reference lacks the sodium chloride of instant claim 13, which qualifies as a Group I salt, as claimed instantly in claim 3.

Remington's teaches that a knowledge of colligative properties of solutions is essential for one to understand fully the principles involved in rendering intravenous solutions isotonic with blood serum...to produce less shock and less irritation than those which are hypotonic or hypertonic, and present-day practice recognizes the desirability of making the necessary adjustments whenever possible. Finally, the secondary reference teaches that the usual practice is to add either sodium chloride or dextrose to adjust hypotonic intravenous solutions to isotonicity. See: page 1405, col. 1, line 1 – page 1406, col. 1, line 34.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the isotonicity of the injectible formulation of

Ropapharm by adjusting the tonicity of the solution using sodium chloride, the salt which is usually used for adjusting tonicity of injectible solutions because of the reasonable expectation that sodium chloride would adjust the formulation, to produce less shock and less irritation.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Clinton Ostrup whose telephone number is (703) 308-3627. The examiner can normally be reached on 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Clinton Ostrup
Examiner
Art Unit 1614

Frederick Krass
Primary Examiner
Art Unit 1614

June 23, 2003